

MEMORANDUM

SUBJECT: Phosmet - Review of Incident Reports for ProTICall®
Derma-Dip (Reg. No. 773-79)

DP Barcode: D234382
PC Code: 059201
Case: 031376
Submission: S520344

FROM: Virginia A. Dobozy, V.M.D., M.P.H., Veterinary Medical
Officer
Review Section I, Toxicology Branch II
Health Effects Division (7509C)

TO: Michael Metzger, Branch Chief
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

and

George LaRocca/Adam Heywood/PM 13
Registration Division (7505C)

THRU: Jess Rowland, M.S., Acting Section Head
Review Section I, Toxicology Branch II
Health Effects Division (7509C)

and

Yiannakis M. Ioannou, Ph.D., Acting Branch Chief
Toxicology Branch II
Health Effects Division (7509C)

Action Requested: Review incident reports for Derma-Dip which were
submitted as follow-up to May 30, 1996 meeting with registrant,
Mallinckrodt Veterinary.

Recommendations: The total number of incidents since registration
of Derma-Dip is low, however there is evidence of misuse in cats
and other domestic animals. The label for ProTICall® Derma-Dip
should be revised in accordance with PR Notice 96-6. Specific
language to prevent misuse should state, "**USE ONLY ON DOGS. Do not
use on cats or other animals.**" Due to the high incidence of adverse

effects in Pomeranian dogs, any other reports of adverse effects in this breed should be reported immediately to OPP. Contraindication of use in this breed should be considered if this occurs.

Review of Incidents Submitted by Mallinckrodt

Defend Derma-Dip (Reg. No. 773-79), containing 11.6% phosmet, was registered in July 1992 and is sold only through veterinarians. The trade name is presently ProTICall Derma-Dip. The following is a summary of the product sales and incident data for domestic animals (DA) and humans (H) for the three years following registration (from Memo of Understanding of the May 30, 1996 meeting).

<u>Year</u>	<u>Gals. Sold</u>	<u># Calls</u>	<u>Adv. Eff. (DA)</u>	<u>Adv. Eff. (H)</u>
93/94	1563	14	0	0
94/95	1250	22	8	1
95/96	1627	13	3	0

In the June 20, 1996 correspondence, revised figures for unit sales were submitted, as follows.

<u>Year</u>	<u>Gallon Sales</u>	<u>12 X 4 oz. Sales</u>
1993	1080	2273
1994	1195	3044
1995	171	4473

Individual reports were submitted for the adverse effect incidents. In 94/95, the incidents involved 3 dogs, 3 cats and 2 ferrets; of these, 1 cat died. The cases in cats and ferrets resulted from misuse. In 95/96, the three reports of incidents involved 2 dogs and 2 cats; of these, 1 dog and 1 cat died. The cases in cats were the result of misuse. The report of a human adverse reaction involved groomers who experienced headaches and blurred vision after application of the dip. The Memorandum of Understanding of the May 30, 1996 meeting with the registrant states that this case was investigated and all of the findings relative to the incident were submitted to the Agency. The groomers did not follow label directions nor did the veterinary hospital where they were employed enforce the wearing of protective clothing. Neither of the two young women involved sought medical attention, as suggested by Mallinckrodt.

Review of Incidents Submitted by McKenna & Cuneo

On February 12, 1997, McKenna & Cuneo, a law firm which audited Mallinckrodt Veterinary for compliance with FIFRA 6(a)(2), forwarded a backlog of incident reports which had not been previously submitted to OPP. There were 1 human and 6 animal cases for Defend Derma-Dip with this submission. One case from 93/94 involved a cat which had convulsions after application of the

product (misuse). The four cases from 94/95 involved 1 dog, 1 cat and 2 ferrets; the cat and ferret cases were also referenced in the Mallinckrodt submission described above.

Review of Incidents in Incident Data System (IDS)

As of March 18, 1997, there were 12 incident reports in IDS for Derma-Dip. Seven included those reports forwarded by McKenna & Cuneo and three were repeats of the reports submitted by Mallinckrodt. There were two cases which occurred in 1996 and were not included in either of the data bases described above. One 8 week-old Pomeranian puppy was bathed with an insecticidal shampoo and then dipped with Derma-Dip. The dog became limp, developed breathing problems, seizures and died. In the other case, a 5-6 week-old beagle puppy vomited after treatment and died shortly thereafter. This is a misuse since the label restricts use to dogs over 8 weeks of age.

Total Number of Incidents

Fifteen animals (7 dogs, 6 cats and 2 ferrets) have been involved in incidents of adverse reactions with Derma-Dip since its registration. This number appears low in comparison to the amount of product used, based on either of the sales data provided. It is also low compared to the number of incidents reported for other organophosphate pesticides used directly on domestic animals. However, on a list of the top generic chemicals for which the National Animal Poison Control Center received calls in 1992, phosmet was number six for dogs and number nine for cats. (There is no information on how many of these calls involved poisoning incidents.)

PR Notice for Pet Products

In 1996, PR Notice 96-6 was issued to require label revisions for pesticides used directly on pets. Revision of the ProTICall Derma-Dip label in accordance with this Notice should provide risk reduction measures in dogs, the registered species and reduce misuse in other species. Specifically, the label should state "**USE ONLY ON DOGS. Do not use on cats or other animals.**" The other label revisions in the Notice should also be followed.

Conclusions and Recommendations

1. The total number of incidents since registration of Derma-Dip is low, however there is evidence of misuse in cats and other domestic animals. The ProTICall product label should be revised in accordance with PR Notice 96-6. Specific language to prevent misuse should state, "**USE ONLY ON DOGS. Do not use on cats or other animals.**"

2. Three of the seven dogs reported to have adverse effects after Derma-Dip exposure were Pomeranians. Toxicology Branch II is not aware of reports in the literature of unique sensitivity of this

breed to phosmet. However, the registrant should immediately submit any future reports of adverse effects in this breed to OPP. Contraindication of use in this breed should be considered if this occurs.

cc: Jerry Blondell, OREB

Sign-off date: 04/16/97
DP Barcode: D234382
HED DOC Number: "NONE"
Toxicology Branch: TB2